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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,185	01/09/2001	Marina Ziche	ZICHE1	5690

7590 04/22/2003

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EXAMINER	
MITRA, RITA	
ART UNIT	PAPER NUMBER
1653	8

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/756,185	ZICHE ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,6 and 10-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 4, 6 and 10-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

Applicants' amendment and response to the office action dated October 1, 2002, filed on January 2, 2003 (paper #7) is acknowledged. Claims 1, 2, 5 and 7-9 have been canceled. Claims 3, 4 and 6 have been amended and entered. New claims 10-25 have been added. Therefore, claims 3, 4, 6 and 10-25 are currently pending and are under examination.

Response to Remarks and Arguments

Withdrawal of Rejections.

The rejection of claims 1 and 2 under **35 U.S.C. 101,** being a non-statutory subject matter is moot in view of Applicants' cancellation of claims.

The rejection of claims 1, 2, 5 and 7-9 under **35 U.S.C. 112, second paragraph** is moot in view of applicants' cancellation of claims.

The rejection of claims 3, 4 and 6 under **35 U.S.C. 112, second paragraph** is withdrawn in view of Applicants' amendment to claims.

The rejection of claims 7-9 under **Nonstatutory Double Patenting**, is moot in view of applicants' cancellation of claims.

New Grounds of rejection

Rejection under 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

Claims 15, 16, 19 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 16 are indefinite because it is not possible for the separate administration dose because component B and human growth factor are in the same composition.

Claims 19 and 23 are indefinite for the term "relative amount." It is not clear what is that amount which would provide synergistic results. Claims 19 and 23 are also indefinite because it is not clear whether Component B is capable of synergizing with a growth factor or vice versa.

Rejections - Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 6, 19, 23-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,998,364 in view of Folkman J. ("Clinical application of research on angiogenesis", Seminars in medicine of the Beth Israel Hospital, vol 333, No. 26, 1995, Reference AC of IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 11-25 are directed to the broadest scope of the method of treatment of wounds, ulcers and other traumatic

lesions to any of the tissues in the body. Claims 11-25 encompass the administering an effective amount of Component B set forth in claim 1 of patent US '364.

Claims 11-25 disclose a method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, comprising administering in a single administrative dose an effective amount of component B and an effective amount of a human growth factor. This is an obvious variation of claim 1 in the patent '364, which discloses a method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, comprising administering an effective amount of component B, together with a pharmaceutically acceptable carrier. These claims practice the invention of claim 1 of '364.

Thus, claims 11-25 in present application and claim 1 in the patent '364 are obvious variations of a method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, comprising administering in a single administrative dose an effective amount of component B and an effective amount of a human growth factor. Any of claims 11-25in the current application would anticipate claim 1in the '364 patent.

Folkman teaches several angiogenic proteins e.g. bFGF and vEGF , whose angiogenic activity can be synergistic (see page 1757, col 2, lines 13-19). This addresses claims 3, 6, 19, 23, 24 and 25 of the instant application. Furthermore Folkman does not teach a composition that comprises Component B as claimed in claim 1 of patent '364. Therefore, claims 3, 6, 19, 23, 24 and 25 in the present application and claim 1 in the patent'364 are obvious variations of a method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, comprising administering in a single administrative dose an effective amount of component B and an effective amount of a human growth factor. The current claims would anticipate the '364 patent claim. The '364 patent claim in combination with the Folkman reference teach the combined composition and the currently claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 6, 11, 12, 19, 20, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martelli F. (WO 97/39765, October 30, 1997, Reference AB of IDS) taken with Folkman J. ("Clinical application of research on angiogenesis", Seminars in medicine of the Beth Israel Hospital, vol 333, No. 26, 1995, Reference AC of IDS).

Martelli discloses a pharmaceutical composition comprising component B as active ingredient, together with a pharmaceutically acceptable carrier (see claim 3 and also page 13). Martelli also teaches a method of treatment of wounds, ulcers and other traumatic lesions to any of the tissues in the body, comprising administering an effective amount of Component B, together with a pharmaceutically acceptable carrier (see claim 4 and pages 1-2). This addresses claims 3, 11, 12 and 20 of the instant application. In view of the fact that the reference teaches both composition and method of treatment using Component B, it would have been obvious to and motivated one of ordinary skill in the art to have combined the teachings with those of, Folkman J.

Folkman teaches several angiogenic proteins e.g. bFGF and vEGF , whose angiogenic activity can be synergistic (see page 1757, col 2, lines 13-19). This addresses claims 3, 6, 19, 23, 24 and 25 of the instant application. Furthermore Folkman does not teach a composition that comprises Component B as claimed in claims 3 and its dependent claims 3, 4, 6 and 10. In view of the fact that Martelli reference teaches Component B in a composition, it would have been obvious to and motivated one of ordinary skill in the art to have combined Martelli's Component B with Folkman's angiogenic protein to give synergistic results as claimed in claims 19, 23, 24 and 25.

Thus the combined references would have resulted in the claimed invention which was *prima facie* obvious to make and use at the time it was made.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

R Mitra

Rita Mitra, Ph.D.
April 18, 2003

Christopher S. Low

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